UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: September 12, 2005

SUBJECT: Efficacy Review for Perasan A
EPA Reg. No. 63838-1;
DP Barcode: D318059

FROM: Lorilyn M. Montford LMM 9/15/05
Efficacy Evaluation Team
Antimicrobials Division (7510C)

THROUGH: Nancy Whyte, Acting Team Leader
Efficacy Evaluation Team
Antimicrobials Division (7510C)
Sept. 15, 2005

TO: Marshall Swindell, PM 33/Tony Kish
Regulatory Management Branch I
Antimicrobials Division (7510C)

APPLICANT: EnviroTech Chemical Services, Inc.
500 Winmoore Way
Modesto, CA 95358

FORMULATION:

Active Ingredient(s)	% by wt.
Peroxyacetic Acid	5.6%
Hydrogen Peroxide	26.5%
Inert Ingredient(s)	67.9%
Total	100.00%

I BACKGROUND

The product, PERASAN® A (EPA Reg No. 63838-1), is an EPA -approved food contact surface disinfectant/sanitizer for use on hard, non-porous surfaces. In a previous submission, the applicant requested an amendment to the registration of this product to decrease the food contact sanitizer dose from 1 oz of product per 5 gallons of water to 1 oz of product per 6 gallons of water. This data submission is part of the requested final report (see Agency letter dated February 17, 2005) that the applicant must submit to not only confirm that the chosen neutralizer is effective and not toxic to the test organisms, but to also support the original stated amendment.

This data package contained three studies (MRID Nos. 465551-01, 465551-02 and 46565-01), Statements of No Confidentiality Claims for all studies, 5 copies of the proposed label.

II USE DIRECTIONS

The product is designed to be used for sanitizing precleaned surfaces such as equipment, pipelines, tanks, vats, filters, evaporators, pasturizers, and aseptic equipment in daires, wineries, beverage and food processing/packing plants and eating establishments. The product is also designed to sanitize and disinfect floors, walls, and other hard non-porous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, bed frames, shelves, racks, carts, refrigerators, coolers and other glass and stainless steel surfaces. Directions on the last accepted label (dated May 20, 2003) provide the following information preparation and use of the product as a food-contact surface sanitizer: Prior to sanitizing, remove gross food particles, then wash with a detergent solution, followed by a potable rinse. Sanitize with a concentration of 1.0 ounce PERASAN A dissolved in 5 gallons of water (0.16% v/v concentration, or 98 ppm active peroxyacetic acid).....Use immersion, coarse spray or circulation techniques as appropriate to the equipment. All surfaces should be exposed to sanitizing solution for a period of at least 60 seconds or more if specified by a governing code. Drain thoroughly and allow to air dry. Do not rinse. Use dilutions up to 2.0 oz of this product per 5 gallons of water (197 ppm peroxyacetic acid) may be used.

The directions also provide the following instructions for disinfection of poultry premises: For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use. Remove all poultry and feeds from premises, trucks, coops, crates. Remove all liter droppings from floors, walls, and surfaces of facilities occupied or traversed by poultry....Thoroughly clean all surfaces with a detergent and rinse with water. Saturate surfaces with a 0.16% (1.0 oz./5gal.) Solution of PERASAN A for a period of 10 minutes. Thoroughly scrub treated feed racks.....rinse with potable water before use.

III COMMENTS ON SUBMITTED EFFICACY STUDIES

1. MRID #465551-01 "Modified EPA food Contact Sanitizer Test For Previously Cleaned Food-Contact Surfaces (AOAC Germicidal and Detergent Sanitizing Action of Disinfectant" by Daniel L. Prince, Ph.D. Study conducted by Gibraltar Laboratory, Inc. Study completion date - May 12, 2005

This study was conducted against *Bacillus subtilis var. globigii* (ATCC #49760), *Byssochlamys fulva* (ATCC #24474) and *Aspergillus niger* (ATCC# 16404). One lot (Lot No. 35-411021) of product, Perasan, was tested using a modification of the AOAC Germicidal and Detergent Sanitizing Action of Disinfectant Test, as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. Four mL of the test substance was added to 508 mL of 400ppm AOAC hard water (volume to volume) to equal 391 ppm active and ten mL of test substance was added to 502 mL of 400 ppm AOAC hard water (volume to volume) to equal 977 ppm active. Next, 99 mL of water to be used in the test, containing bactericide at the concentration to be tested, was measured into sterile Erlenmeyer flasks and placed in a constant temperature bath until reaching 46±1.0C and 60±1.0C for ≥ 20 minutes. One mL of culture suspension was added to each flask. Flasks were whirled. The suspension was added with tip of pipet slightly immersed in the test solution. For test samples, one mL of exposed culture was added to to neutralizer blank exactly 15 seconds after the addition of the suspension and mixed well immediately after transfer. One mL of exposed culture was transferred into 99mL of neutralization broth. The flask was shaken and one 90mL of aliquot (dilution 10^{-2}) and 10mL aliquot (dilution 10^{-3}) were membrane filtered through 0.45 micron membrane filters and plated onto individual sterile petri dishes containing Trypticase Soy Agar (bacteria) and Sabourand Dextrose Agar (molds). Controls included neutralization effectiveness, sterility, number control, neutralization system toxicity.

2. MRID #465551-02 "Modified EPA food Contact Sanitizer Test For Previously Cleaned Food-Contact Surfaces (AOAC Germicidal and Detergent Sanitizing Action of Disinfectant" by Daniel L. Prince, Ph.D. Study conducted by Gibraltar Laboratory, Inc. Study completion date - April 21, 2004

This study was conducted against *Salmonella choleraesuis* (ATCC #10708), and *Listeria monocytogenes* (ATCC# 984). Two lots of product (one greater than 60 days old) (Lot No. 35-411021 and 35-410152) of product, Perasan, was tested using a modification of the AOAC Germicidal and Detergent Sanitizing Action of Disinfectant Test, as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. One mL of the test substance was added to 767 mL of 400ppm AOAC hard water (volume to volume) to equal 72.9 ppm active. 99 mL of water to be used in the test, containing bactericide at the concentration to be tested, was measured into sterile, 250 mL wide-mouth Erlenmeyer flasks and placed in a constant temperature bath until it reached 25 ± 0.2C, for ≥ 20 min. Duplicate germicide flasks were prepared for each germicide. A similar flask was also prepared containg 99 mL sterile phosphate buffer dilution H_2O. One mL culture suspension was added to each test flask. The flasks was whirled. One mL portions of the exposed culture were added to neutralizer blanks exactly 30 seconds and 60 seconds after the

addition of the suspension and mixed well immediately after transfer. The flask The flask was shaken and one 90mL of aliquot (dilution 10^{-2}) and 10mL aliquot (dilution 10^{-3}) were membrane filtered through 0.45 micron membrane filters and plated onto individual sterile petri dishes containing Trypticase Soy Agar (bacteria). Controls included neutralization effectiveness, sterility, number control, neutralization system toxicity.

3. MRID# 46565-01, "AOAC Germicidal and Detergent Sanitizing Action of Disinfectant" by Daniel L. Prince. Ph.D. Study conducted by Gibraltar Laboratories, Inc. Study completion date - April 20, 2005

This study was conducted against *Staphylococcus aureus*(ATCC #6538), and *Escherichia coli* (ATCC# 11229). Three lots of product (one greater than 60 days old) (Lot No. 35-411021, 35-410152, and 35-412131) of product, Perasan, was tested using a modification of the AOAC Germicidal and Detergent Sanitizing Action of Disinfectant Test, as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. One mL of the test substance was added to 767 mL of 400ppm AOAC hard water (volume to volume) to equal 72.9 ppm active. 99 mL of water to be used in the test, containing bactericide at the concentration to be tested, was measured into sterile, 250 mL wide-mouth Erlenmeyer flasks and placed in a constant temperature bath until it reached 25 $\pm$ 0.2C, for $\geq$ 20 min. Duplicate germicide flasks were prepared for each germicide. A similar flask was also prepared containing 99 mL sterile phosphate buffer dilution H_2O. One mL culture suspension was added to each test flask. The flasks was whirled. One mL portions of the exposed culture were added to neutralizer blanks exactly 30 seconds and 60 seconds after the addition of the suspension and mixed well immediately after transfer. The flask The flask was shaken and one 90mL of aliquot (dilution 10^{-2}) and 10mL aliquot (dilution 10^{-3}) were membrane filtered through 0.45 micron membrane filters and plated onto individual sterile petri dishes containing Trypticase Soy Agar (bacteria). Controls included neutralization effectiveness, sterility, number control, neutralization system toxicity.

IV RESULTS

Table 1: Calculated Results for *Aspergillus niger* (cfu/mL)

Concentration in ppm (v/v)	Exposure Time	Test Temperature	Average Number Surviving (cfu/mL)	Microbes Initially Present (cfu/mL)	Microbes Initially Present (Log_{10})	Log_{10} Reduction	Percent Reduction
391 ppm	15 seconds	46C	3.1×10^3	4.0×10^7	7.6	4.11	>99.99%
	15 seconds	60C	0	4.0×10^7	7.6	7.6	>99.99%
977 ppm	15 seconds	46C	0	4.0×10^7	7.6	7.6	>99.999%
	15 seconds	60C	0	4.0×10^7	7.6	7.6	>99.999%

Table 2. Calculated Results for *Bacillus subtilis var. globigii* (cfu/mL)

Concentration in ppm (v/v)	Exposure Time	Test Temperature	Average Number Surviving (cfu/mL)	Microbes Initially Present (cfu/mL)	Microbes Initially Present (Log_{10})	Log_{10} Reduction	Percent Reduction
391 ppm	15 seconds	46C	TNTC	8.1×10^7	7.91	0	>99.99%
	15 seconds	60C	1.2×10^4	8.1×10^7	7.91	3.83	>99.99%
977 ppm	15 seconds	46C	0	8.1×10^7	7.91	7.91	>99.999%
	15 seconds	60C	0	8.1×10^7	7.91	7.91	>99.999%

Table 3. Calculated Results for *Byssochlamys fulva* (cfu/mL)

Concentration in ppm (v/v)	Exposure Time	Test Temperature	Average Number Surviving (cfu/mL)	Microbes Initially Present (cfu/mL)	Microbes Initially Present (Log_{10})	Log_{10} Reduction	Percent Reduction
391 ppm	15 seconds	46C	0	1.7×10^6	6.23	6.23	>99.999%
	15 seconds	60C	0	1.7×10^6	6.23	6.23	>99.999%
977 ppm	15 seconds	46C	0	1.7×10^6	6.23	6.23	>99.999%
	15 seconds	60C	0	1.7×10^6	6.23	6.23	>99.999%

Table 4. Calculated Results for *Salmonella choleraesuis* (cfu/mL)

Test Substance	Exposure Time	Concentration in ppm (v/v)	Average Number Surviving (cfu/mL)	Microbes Initially Present (cfu/mL)	Microbes Initially Present (Log_{10})	Log_{10} Reduction	Percent Reduction
Perasan A Lot#35-411021	30 seconds	72.9	0	8.3×10^7	7.92	7.92	>99.999%
Perasan A Lot# 35-410152	30 seconds	72.9	0	8.3×10^7	7.92	7.92	>99.999%

Table 5. Calculated Results for *Listeria monocytogenes* (cfu/mL)

Test Substance	Exposure Time	Concentration in ppm (v/v)	Average Number Surviving (cfu/mL)	Microbes Initially Present (cfu/mL)	Microbes Initially Present (Log_{10})	Log_{10} Reduction	Percent Reduction
Perasan A Lot#35-411021	30 seconds	72.9	0	7.9×10^7	7.9	7.9	>99.999%
Perasan A Lot# 35-410152	30 seconds	72.9	0	7.9×10^7	7.9	7.9	>99.999%

Table 6. Calculated Results for Escherichia coli (cfu/mL)

Test Substance	Exposure Time	Concentration in ppm (v/v)	Average Number Surviving (cfu/mL)	Microbes Initially Present (cfu/mL)	Microbes Initially Present (Log_{10})	Log_{10} Reduction	Percent Reduction
Perasan A Lot#35-411021	30 seconds	72.9	0	8.9×10^7	7.95	7.95	>99.999%
Perasan A Lot# 35-410152	30 seconds	72.9	0	8.9×10^7	7.95	7.95	>99.999%
Perasan A Lot #35-412131	30 seconds	72.9	0	8.9×10^7	7.95	7.95	>99.999%

Table 7. Calculated Results for Staphylococcus aureus (cfu/mL)

Test Substance	Exposure Time	Concentration in ppm (v/v)	Average Number Surviving (cfu/mL)	Microbes Initially Present (cfu/mL)	Microbes Initially Present (Log_{10})	Log_{10} Reduction	Percent Reduction
Perasan A Lot#35-411021	30 seconds	72.9	85	1.1×10^8	8.00	6.07	>99.999%
Perasan A Lot# 35-410152	30 seconds	72.9	79	1.1×10^8	8.00	6.10	>99.999%
Perasan A Lot #35-412131	30 seconds	72.9	74	1.1×10^8	8.00	6.13	>99.999%

V. CONCLUSIONS

1. The submitted efficacy data (MRID 465551-01) does support the use of the product, Perasan A, as a food contact surface sanitizer/disinfectant when tested against *Aspergillis niger, Byssochlamys fulva*, and *Bacillus subtilis var. niger*, on hard, non-porous surfaces for a contact time of 15 seconds.

2. The submitted efficacy data (MRID 465551-02) does support the use of the product, Perasan A, as a food contact surface sanitizer/disinfectant when tested against *Salmonella choleraesuis*, and *Listeria monocytogenes*, on hard non-porous surfaces for a contact time of 30 seconds.

3. The submitted efficacy data (MRID 465651-01 does support the use of the product, Perasan A, as a food contact surface sanitizer/disinfectant when tested against *Staphylococcus aureus*, and *Escherichia coli*, on hard, non-porous surfaces for a contact time of 30 seconds.

VI RECOMMENDATIONS

1. The label claims (as supported by MRID No. 465551-01) are acceptable regarding the use of the product, Perasan A as a food contact surface sanitizer/disinfectant against *Aspergillis niger, Byssochlamys fulva*, and *Bacillus subtilis var. niger*, on hard, non-porous surfaces for a contact time of 15 seconds.

2. The label claims (as supported by MRID No. 465551-02) are acceptable regarding the use of the product, Perasan A as a food contact surface sanitizer/disinfectant against *Salmonella choleraesuis*, and *Listeria monocytogenes*, on hard, non-porous surfaces for a contact time of 30 seconds.

3. The label claims (as supported by MRID No. 465651-01) are acceptable regarding the use of the product, Perasan A, as a food contact surface sanitizer/disinfectant against *Staphylococcus aureus*, and *Escherichia coli*, on hard, non-porous surfaces for a contact time of 30 seconds.